Kansas Medical Assistance Program

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

March 10, 2004

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session SRS Learning Center, Conference Rooms A & B Topeka, Kansas March 10, 2004	**Members Present:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph.; Brenda Schewe, M.D.; Kevin Waite, PharmD; John Whitehead, D.O. **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Vicki Schmidt, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.	**Representatives:** Mike Hutfles (Ks Governmental Consulting), Bruce Steinberg (Aventis), James Lieurance (Takeda), Craig Boon, R.Ph. (Heritage Information Systems, Inc.), Chris Johnson (Heritage Information Systems, Inc), Susan Zalenski (Sanofi-Synthelabo), Danny Ottosen (Berteck Pharmaceuticals), Mike Moratz (Merck), Barbara Belcher (Merck), Mahendra Sahadeo (Pfizer), Jared Lurk (Aventis), Jay Morris (Pfizer), Kellie Hooper (LifeScan), Ann Gustafson (GlaxoSmithKline), Brett Spencer (Purdue Pharma)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Brenda Schewe, Acting Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:40a.m.	
II. Review and Approval of January 14, 2004, Meeting Minutes	• One correction was made by Barry Sarvis to the January 14, 2004 meeting minutes. Page 4, under Decision/Action, remove Serevent, Accolate, Zyflo.	• A motion to approve the minutes with the correction was made by Dr. Whitehead and seconded by Mr. Sarvis. The motion carried unanimously by a roll call.
III. New Business **A. Xenical** **Discussion of Prior Authorization Criteria**	• Mary informed the DUR Board that the FDA has approved Xenical for ages 12 and up. The criteria has stayed the same.	

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	• Dr. Schewe asked, how many people were denied Xenical after 3 months that didn't lose 5%. • Dr. Grauer stated that when the University of Kansas did a study on dietary drugs, it showed that around 65%-70% were denied Xenical after 3 months. • Dr. Schewe asked if the age limits would eventually be listed on the criteria form. Vicki answered that the ages would be listed on the guidance sheet that the prior authorization unit uses. • Ms. Kroeger asked about beneficiaries only receiving Xenical once a lifetime. Mary stated that the beneficiaries can take each dietary drug once a lifetime if all criteria is met for approval. Ms. Kroeger pointed out that it sometimes takes 4 to 5 tries for some people to lose weight. Mary explained that studies show that losing weight also depends on diet and exercise. • Dr. Schewe pointed out that the State allows smokers to receive smoking cessation drugs once per year. Ms. Kroeger stated that she thinks Xenical should be allowed more than once a lifetime. • Dr. Waite pointed out that the criteria doesn't prevent beneficiaries from trying to diet without drugs. • Vicki pointed out that if a physician feels that there patient should receive Xenical again, they can send in the prior authorization form and it will go through the appeal process. This is a time consuming process. • Mary stated that one option could be for an	• Dr. Grauer will supply a copy of the study to Vicki.

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Public Comment **DUR Board Recommendation**	addition to be made to the criteria allowing the physician to indicate that the patient would benefit from an additional approval and thereby by passing the appeal process. • Vicki pointed out that the DUR Board originally reviewed this drug in 1999 and then it was very controversial to cover this drug. • No Public comment. • With no further discussion, a motion was placed before the Board.	• After further discussion regarding the benefit of an additional course of therapy, it was decided that Mary would bring some suggested exceptions to the next DUR Board meeting. • A motion was made by Ms. Kroeger and seconded by Dr. Grauer to accept the addition of 12 and older to the Xenical criteria. Mary will bring Xenical back to the DUR Board with recommendations of how often a patient can receive dietary drugs. The motion carried unanimously by roll call.
B. Paxil use 18 Years of Age and Younger **Discussion of Appropriate Use**	• Vicki introduced Chris Johnson, R.Ph. (Heritage Information Systems) and Craig Boon (Heritage Information Systems) to the DUR Board. Vicki stated that Heritage will help with this discussion by discussing the possibility of including Paxil and other anti-depressants in an intervention. She stated that the FDA has sent out a warning that Paxil possibly increases the risk of suicidal impulses in children under the age of 18. The FDA only approves Luvox for 8-17 years of age, Zoloft for 6-12 years of age, and Prozac for 8-18 years of age. She then reviewed the anti-depressant hand out.	

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Paxil - Continued **Public Comment** **DUR Board Recommendation**	• Chris Johnson (Heritage) stated that his tendency is to address this entire class of drugs. He stated that Heritage could do an analysis that would include all unique age requirements for each product. They could also compare patient supportive diagnosis. There are usually a portion of patients with no diagnostic support. Many times the family physician's name is tied to the claim when the patient is seeing a child psychologist. The family physician is not always aware of the treatment that is occurring simultaneously with the child psychologist. • The information presented did not have diagnosis codes. This was done using the FDA guidelines for dosage. Off label uses may be addressed in an intervention. • No public comment.	• Heritage will look at the data and propose an intervention at the next DUR meeting.
C. Expenditures for Calendar Year 2003	• Vicki stated that this is one tool that can be used through Business Planformance. Vicki then reviewed and explained the expenditures for calendar year 2003. • Barbara Belcher (Merck) asked if the percentage of growth column was figured by number of prescriptions or number of dollars. Vicki answered that this report was run by the amount paid.	• The DUR Board requested that this report be run again by prescription instead of cost and be available at the next DUR meeting.

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D. Heritage – Craig Boon		
Second Quarter 2004 Proposed Intervention -Diabetes Mellitus Disease Management	• Chris (Heritage) pointed out that Heritage could do the Paxil intervention first and then do the diabetes intervention or they could do the diabetes intervention first and then move on to Paxil, since the Paxil intervention will need to be designed. • The DUR Board discussed that the diabetes intervention would benefit a larger portion of the population. • In the previous interventions, all prescribers that are "flagged" for an intervention received letters. The intervention letters are then reinforced with the newsletter. Six months after the intervention a follow-up is done by Heritage to review the effectiveness.	
DUR Board Recommendation	• With no further discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Waite to continue with the diabetes intervention and then do the Paxil intervention. The motion carried unanimously by a roll call vote.
First Quarter 2004 Intervention- Hyperlipidemia - Update	• Craig (Heritage) stated that the Hyperlipidemia intervention was mailed out. There were a total of 1634 letters sent out to physicians. Heritage has started to receive comments from physicians for earlier mailings. Since the physicians are not required to respond to the interventions, most of the response is by phone. • Dr. Burke asked how many physicians are in Kansas. Craig (Heritage) stated that Heritage originally sent out around 10,000 newsletters, approximately 3,500 were duplicate or returned for an invalid address. There is an estimated 6,500 physicians in Kansas. Both ARNP's and PA's receive intervention letters.	

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Public Comment	• Bruce Steinberg (Aventis) had a question regarding the diabetes intervention. He stated that Heritage is measuring the criteria on diabetes by the complications instead of the outcome. Chris (Heritage) stated that what Heritage is looking at is if an A1C is ordered. The results of the A1C are not available to Heritage. Dr. Grauer stated that the test results aren't an outcome either. The outcome should be the quality of life. Jared Lurk (Aventis) recommended that the diabetes intervention should include the full scope, not just oral hypoglycemics. This should be expanded to include insulin products. Dr. Burke pointed out that we use the data that we receive from the State to make decisions, and the difficulty is the monitoring of insulin usage with this data. Jared Lurk (Aventis) stated that he is not requesting for the State to monitor insulin use. He is asking for insulin to be included in the intervention. He thinks it is limiting to target oral agents only. Dr. Schewe asked if a patient is diabetic and not taking an oral hypoglycemics are they going to be skipped or will they also be flagged? Craig (Heritage) stated that diabetic patients taking insulin will most likely be flagged because of one of the other performance indicators. For example, all patients will be flagged that have a diabetic ICD9 diagnosis. Chris (Heritage) stated that this will include some patients that are receiving insulin. It is almost impossible to monitor compliance with insulin. Dr. Burke stated that it might be a good idea to include in the intervention letter that some patients on insulin therapy may not have been checked, so people won't see this as the final word.	

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Newsletter Suggestions	• Craig (Heritage) stated that in the previous newsletters they have addressed the relevance of the interventions. Information about diabetes, including insulin therapy, could be included in the newsletter. • Dr. Burke asked if there was a projected schedule for newsletter topics. Vicki stated that there is no projected schedule because the newsletter topics have followed the interventions. The pharmacies are not receiving intervention letters, but they are receiving the newsletters. • Dr. Burke asked if the DUR Board member's names could be listed on the back of the newsletters. • Dr. Burke stated that it would also be a good idea to have Preferred Drug List information and Center for Evidence-based Policy information listed on the back. • Chris (Heritage) suggested that Heritage could also list utilization information. • Barbara Belcher (Merck) asked if the newsletter is available online or can pharmaceutical representatives receive a copy. • Barbara Belcher (Merck) asked if it would be possible for the agendas and packet information to be emailed out to everyone. Vicki stated that we have considered that, the problem with that is that some files are too big. We are currently working on a DUR website. We would eventually like to post all DUR information on the website.	• The newsletter will list the DUR Board members. • Future newsletters will include this information. • Newsletters will be emailed to the DUR meeting list until the DUR website is functioning.

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D. Update on PDL and Evidence – based Policy Presentation – Mary Obley	• Mary stated that on February 18, 2004 we had a meeting with Dr. John Santa – Center for Evidence-based Policy. He talked to the PDL, DUR, PERC, and drug manufacturers. This meeting went very well, there were lots of questions and answers. The PDL will still work the same; this is a way for the PDL to receive non-biased information. • Dr. Burke stated that we have used information from the Center for Evidence-based Policy in the past. • Barbara Belcher (Merck) asked why we joined the Center for Evidence-based Policy if we can get the information off the web without paying. • Mary stated that by joining the Center for Evidence-based Policy the State of Kansas is able to suggest the key question, etc… Reports are received before the public release. In addition the Center provides support for the PDL committee.	
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Mr. Sarvis and seconded by Dr. Bryant to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:15 a.m.